

REMARKS

The final Office Action of July 27, 2001 has been received and carefully reviewed, and the comments set forth below are a complete response thereto.

Claims 1-3 and 5-54 are all the pending claims for this application. Claims 6-17 and 21-54 have been withdrawn from prosecution for being drawn to non-elected subject matter.

The peptide sequences for SEQ ID NOS: 1-7 have been found to be free of prior art.

By this Amendment, claim 1 has been amended to delete the term “essentially” and that portion of element (h) reciting “wherein the peptide or peptide derivative has isoleucine as the C-terminal amino acid” as claimed in Claim 1 of the Amendment of January 10, 2001. Amended Claim 1 is now directed to a “peptide or peptide derivative of SEQ ID NO. 7 comprising a C-terminal isoleucine” and element (i) of Claim 1 now recites “human MHC molecules”.

No new matter has been added, and consideration and entry of the amended claims is requested.

I. Response to Withdrawal of Claims 53 and 54/ Withdrawal of Election of Species Requirement

In the Office Action, the Examiner states that Claim 53 is drawn to a non-elected species of Group I and claim 54 is drawn to the peptide/MHC complex of non-elected

Group II, whereas the elected group I is drawn to a peptide. Pursuant to 37 CFR §1.142(b), claims 53 and 54 along with non-elected claims 6-7 and 21-52 have been withdrawn as being directed to non-elected inventions.


However, the Examiner has extended the search for the elected species (SEQ ID NO: 7 and a derivative comprising a partial region of SEQ ID NO: 7) to cover SEQ ID NOS: 1-6 and derivatives comprising a partial region of SEQ ID NO: 7 having isoleucine as the C-terminal amino acid residue, and an amino acid sequence which has an essentially equivalent specificity or/and affinity of binding to MHC molecules as SEQ ID NO: 7.

Applicants respectfully submit that claims 6 and 53 be rejoined in view of the foregoing. Claim 53 depends from claim 6, and which depends from claims 1-3. By extending the search of the elected species to all of SEQ ID Nos. 1-7 of claim 1 of Group I, the Examiner has effectively withdrawn the election of species requirement which originally applied to all of the species of claim 1.

II. Response to Rejection of Claims 1-3, 5 and 18-20 under 35 U.S.C. §112, second paragraph

Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Claim 1 is indefinite in the recitation of "essentially equivalent".



Applicants traverse and submit that the Examiner's rejection of the claims is moot in view the subject matter now claimed in instant claims 1-3, 5 and 18-20. Withdrawal of the rejection is deemed proper.

III. Response to Rejection of Claims 1-3, 5 and 18-20 under 35 U.S.C. §112, first paragraph

Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. §112, first paragraph, for lack of written description support.


According to the Examiner, the recital "wherein the peptide or peptide derivative has isoleucine as the C-terminal amino acid" recited in claim 1, part (h) constitutes new matter since it does not find support in the originally filed application.

The instant specification discloses that the sequence of "peptide (VII)" was shortened by a single amino acid at the C-terminus (isoleucine) (specification on page 6, second paragraph). As a separate issue, the disclosed sequence does not actually appear to be the sequence of peptide VII.

Applicants submit that the Examiner's rejection of the claims has been rendered moot in view of the amendment thereof. Withdrawal of the rejection is deemed proper.

IV. Response to Rejection of Claims 1-3, 5, 18 and 19 under 35 U.S.C. §102(b)

Claims 1-3, 5, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07992.



In the Office Action, the Examiner states that WO 95/07992 teaches a peptide and pharmaceutical composition thereof comprising the peptide VNFFRMVISNPAATHQDIDF which is recited in claims 1 and 18 of WO 95/07992 and which comprises amino acid residues 1-18 of SEQ ID NO: 7 (underlined) of the instant application, and wherein the said peptide is therapeutically labeled with a marker group such as a radioisotope, a drug, a lectin or a toxin, and combined with pharmaceutical additive(s) including oils, i.e., depot adjuvants (especially claims 15, 16, 18, 19, 20, 23, 24, 26, page 28 at lines 5-9, page 27 at lines 19-37).

With regard to instant claim 1, the property of having an essentially equivalent specificity and/or affinity of binding to MHC molecules is considered by the Examiner to be an inherent property of the reference compound. The claimed molecule appears to be the same as the reference absent a showing of any differences.

Instant claim 5 is included in the rejection since the Examiner considers that the peptide comprises a label, for instance, a radioisotope, a drug, a lectin or a toxin (claims 26 and 27 of the reference). Instant claim 18 is included because the peptides are used to treat GAD related autoimmune disorders such as IDDM or stiff man disease. Claim 19 is included because preparations of GAD polypeptides include oil, i.e., an adjuvant or accessory stimulating component (especially page 27 at lines 25-36).

Applicants traverse and submit the following comments in response to this aspect of the Examiner's rejection.

The peptide of the '992 patent has two additional N-terminal amino acid residues, i.e., V and N, that are absent from the instant claimed peptide of SEQ ID NO. 7. More

importantly, SEQ ID NO. 7, contains a C-terminal isoleucine residue, which does not appear in the disclosure of the '992 patent. The isoleucine residue confers "biological activity" on a peptide having the **minimal essential length and amino acid composition** of SEQ ID NO. 7. The criticality of the length and amino acid composition of a peptide of SEQ ID NO. 7 containing a C-terminal isoleucine residue is demonstrated by the instant specification.

Accordingly, the peptide length and amino acid composition of SEQ ID NO. 7 are both critical to conferring improved biological activity over the reference peptide, and therefore, the instant claims are novel and nonobvious.

V. Response to Rejection of Claims 1-3, 5, 18 and 19 under 35 U.S.C. §102(e)

Claims 1-3, 5, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,011,139.

In the Office Action, the Examiner states that USPN 6,011,139 discloses a peptide of length 20 amino acid residues which comprises a partial region of the amino acid sequence of the elected species, SEQ ID NO: 7, FFRMVISNPAATHQDIDFLI of Claim 1. The sequence of the reference peptide is VNFFRMVISNPAATHODIDF (SEQ ID NO: 50 of the reference). With regard to instant claim 1, the property of having an essentially equivalent specificity and/or affinity of binding to MHC molecules is considered an inherent property of the reference compound. The claimed molecule appears to be the same as the art absent a showing of any differences.

Instant claim 5 is included since the Examiner considers that the peptide comprises a label, for instance, a radioisotope, a drug, a lectin or a toxin (especially column 9, lines 57-67). Instant claim 18 is included because the said peptide in a pharmaceutical composition is used to treat GAD-related autoimmune disorders such as IDDM (especially column 2, lines 45-50 and Abstract) or for immunization in vivo (especially column 7, lines 9-8). Claim 19 is included because preparations of GAD polypeptides for immunization include adjuvants, including oil, i.e., an adjuvant or accessory stimulating component (especially column 7, lines 15-16 and column 14, lines 57-66).

Applicants traverse and, for purposes of brevity, respectfully request the incorporation of the comments set forth under Section V. Withdrawal of this aspect of the Examiner's rejection is deemed proper.

VI. Response to Rejection of Claims 1-3, 5 and 18-20 under 35 U.S.C. §103(a)

Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 95/07992 or Patent No. 6,011,139 each in view of Burke et al (U.S. Patent No. 5,750,114).

Since WO 95/07992 or Patent No. 6,011,139 do not teach a composition where the accessory stimulating component is a cytokine, the Examiner cites Burke for teaching an HSV polypeptide vaccine which further comprises immunomodulating cytokines such as IL-2 and a pharmaceutically acceptable carrier (especially column 4, lines 738). Thus, the Examiner considers that it would have been *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition comprising the cytokine of Burke et al and the peptide of WO 95/07992 or Patent No. 6,011,139.

Applicants traverse and respectfully request the incorporation of the comments set forth under Section V. Applicants have demonstrated the criticality of the peptide sequence for SEQ ID No. 7 over the closest single embodiments of each of the references and amended the claims around the teachings of the Examiner's cited references. By establishing patentability over the primary references, Burke falls as a secondary reference, since it does not rectify the deficiencies of either primary reference, and it could not stand alone as a primary reference.

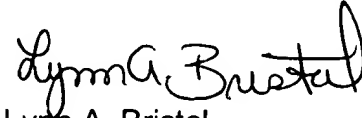
In view of all of the foregoing, Applicants request withdrawal of this rejection.

CONCLUSION

In view of the amended claims and all of the foregoing comments, Applicants respectfully submit that the Examiner's rejection of the claims under 35 U.S.C. §§102(b), 103(a) and the first and second paragraphs of 112, has been met and overcome. Applicants request that the Examiner find the application in condition for allowance, and that the application pass to issuance.

In the event this paper is not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper.

Respectfully submitted,
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MARKED-UP COPY OF CLAIM 1

1. (Five times Amended) Peptide or peptide derivative comprising:

(a) the amino acid sequence (SEQ ID NO:1)

D-V-N-Y-A-F-L-H-A-T-D-L-L-P-A-C-D-G-E-R,

(b) the amino acid sequence (SEQ ID NO:2)

S-N-M-Y-A-M-M-I-A-R-F-K-M-F-P-E-V-K-E-K,

(c) the amino acid sequence (SEQ ID NO:3),

N-W-E-L-A-D-Q-P-Q-N-L-E-E-I-L-M-H-C-Q-T,

(d) the amino acid sequence (SEQ ID NO:4)

T-L-K-Y-A-I-K-T-G-H-P-R-Y-F-N-Q-L-S-T-G,

(e) the amino acid sequence (SEQ ID NO:5)

P-R-Y-F-N-Q-L-S-T-G-L-D-M-V-G-L-A-A-D-W,

(f) the amino acid sequence (SEQ ID NO:6)

T-Y-E-I-A-P-V-F-V-L-L-E-Y-V-T-L-K-K-M-R,

(g) the amino acid sequence (SEQ ID NO:7)

F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I, wherein the peptide or

peptide derivative of SEQ ID NO. 7 comprises a C-terminal isoleucine residue,

(h) a partial region of the amino acid sequence shown in (a), (b), (c),

(d), (e), (f) [or/and] and/or (g) with a length of at least 6 amino acids[,

wherein the peptide or peptide derivative has isoleucine as the C-terminal

amino acid, or/and] and/or

(i) an amino acid sequence which has an [essentially] equivalent specificity [or/and affinity of binding] and/or binding affinity to human MHC molecules as the amino acid sequence shown in (a), (b), (c), (d), (e), (f), (g) [or/and] and/or (h);
wherein said peptide or peptide derivative has a length of up to 25 amino acids.